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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,505	11/23/1999	ROBERT M. GOODMAN	16518.076	3907

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/447,505	Applicant(s) GOODMAN ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-70* is/are pending in the application.

4a) Of the above claim(s) *62-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 15-22, 29, and 30-32, drawn to an expression product of a mammalian viral pathogen gene produced in a transformed dicotyledonous plant cell, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that a search and examination of the entire application would not impose an undue burden on the Office. This is not found persuasive because although the searches for the two groups of invention may overlap, they are not coextensive of each other. A search of Group I would require a search for methods not claimed in Group II, and a search of Group II would require a search for products not claimed in Group I. Furthermore, newly submitted claims 62-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 62-70 are directed to a lysate, comprising a mammalian protein and further comprising degraded plant cell components, which is a distinct product from the isolated expression product of originally presented claims 15-22, 29, and 30-32 and the intact plant cells comprising intact genomes that express a mammalian peptide of newly submitted claims 45-61. Accordingly, claims 62-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dicotyledonous plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide, does not reasonably provide enablement for other types of plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide, or for plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide that has a physiological effect upon ingestion by a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to plant matter comprising plant cells, including seed cells and rapeseed cells, that express a mammalian peptide, including interferon. The claims are also drawn to edible plant matter comprising plant cells that express a mammalian peptide that has a physiological effect upon ingestion by a mammal, including a physiological effect on the regulation of digestion. The claims are additionally drawn to dicotyledonous plant cells, including seed cells and rapeseed cells, comprising a structural gene coding for a mammalian peptide, including interferon.

The specification discloses only the transformation of tobacco to produce plant cells comprising and expressing an isolated nucleic acid coding for murine gamma interferon (pages 15-16). The specification does not disclose the transformation of any other type of plant to produce any other type of plant cells. Furthermore, the specification does not disclose any type

of edible plant matter comprising plant cells that express any type of mammalian peptide that has any type of physiological effect upon ingestion by any mammal.

Guidance for making and using the claimed invention is necessary for enablement because the ability to transform a plant with an isolated nucleic acid is unpredictable. At the time of Applicant's invention (July 1985) only dicotyledonous plants could be reliably transformed with heterologous sequences. For example, Goodman et al. (Science, 1987, Vol. 236, pages 48-54) teach that while *Agrobacterium* mediated gene transfer had become routine for some dicotyledonous plant species, monocotyledonous plants were still considered to be recalcitrant to transformation by *Agrobacterium* (page 52, column 1, second full paragraph). Goodman et al. also teach that the application of direct DNA transfer techniques to monocotyledonous plants had been limited by the general unavailability of techniques for the regeneration of monocotyledonous plants from protoplasts (page 52, column 2, fifth paragraph). Goodman et al. further teach that virally mediated gene transfer to plants was not likely to result in stable transformation of plant cells (page 53, column 1, second full paragraph).

Guidance for making and using the claimed invention is also necessary because the ability of plant cells to express a mammalian peptide such that it has a physiological effect upon ingestion by a mammal is unpredictable. At the time of Applicant's invention little was known about which heterologous peptides expressed in transgenic plant cells would be expressed in a biologically active form, as the biological activity of an expressed peptide could depend on a variety of different factors, such as proteolytic processing, post-translational modification, and/or concentration. For example, Bosch et al. (Transgenic Research, 1994, Vol. 3, pages 304-310) teach that while rainbow trout growth hormone tGH-II mRNA is expressed in transgenic tobacco

leaves and *Arabidopsis* seed, expression of tGH-II protein could only be detected in tobacco leaves, suggesting that the *Arabidopsis* seed cells either failed to translate the tGH-II mRNA, or that the translated tGH-II protein was quickly degraded in the seed cells (page 306, Figure 2; page 307 Figure 3; page 308 column 1, third full paragraph; paragraph spanning pages 308-309). Bosch et al. also teach that cytoplasmically expressed tGH-II is qualitatively different from tGH-II expressed in the secretory pathway. Cytoplasmically expressed tGH-II did not fold correctly and was partially degraded, whereas tGH-II expressed in the secretory pathway was correctly folded and partially glycosylated (page 307 paragraph spanning columns 1 and 2, Figures 3 and 4). Additionally, Bosch et al. teach that tGH-II was not expressed in quantities sufficient to assay for biological activity, and that the quantities produced were probably too low for commercial applications as well (page 309 column 1 second full paragraph).

Furthermore, at the time of Applicant's invention it was also known that some peptides were subject to proteolytic degradation upon ingestion by an animal, such that even a peptide expressed in a biologically active form and at an effective concentration could be inactivated upon ingestion. For example, Wallace et al. teach that oral administration of peptide and protein based drugs is considered to be problematic because proteins and peptides are susceptible to enzymatic degradation upon ingestion (Science, 1993, Vol. 260, pages 912-913).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to determine how to transform plants other than dicotyledonous plants with a structural gene coding for a mammalian peptide, and how to express a gene coding for a mammalian peptide in a

plant cell in such a way that the expressed peptide would have a physiological effect upon ingestion by a mammal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52, and claim 53 dependent thereon, is indefinite in the recitation of "physiological effect", because many different aspects of mammalian physiology may be affected by the ingestion of a peptide, and because the nature of the effects depends on the nature of the peptide ingested.

Claim 53 is indefinite in the recitation of "regulation of digestive function", because many different aspects of digestive function may be affected by the ingestion of a peptide, because digestive function may be regulated in a variety of different ways, and because the type of regulation and the nature of the function regulated depend on the nature of the peptide ingested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 11 of U.S. Patent No. 6,096,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 45-61 of the instant application are directed to plant matter comprising plant cells, including seed cells, rapeseed cells and tobacco cells, expressing a mammalian peptide, and dicotyledonous plants cells, including seed cells, rapeseed cells and tobacco cells, comprising a structural gene coding for a mammalian peptide, whereas claims 10 and 11 of U.S. Patent No. 6,096,547 are directed to dicotyledonous plant cells, including tobacco cells, comprising a structural gene coding for a mammalian peptide. The claims are coextensive.

Claims 45-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,629,175. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 45-61 of the instant application are directed to plant matter comprising plant cells, including seed cells, rapeseed cells and tobacco cells, expressing a mammalian peptide, and dicotyledonous plants cells, including seed cells, rapeseed cells and tobacco cells, comprising a structural gene coding for a mammalian peptide, whereas claims 1-8 of U.S. Patent No.

5,629,175 are directed to methods utilizing dicotyledonous plant cells, including tobacco cells, comprising a structural gene coding for a mammalian peptide.

Claims 45-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,550,038. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 45-61 of the instant application are directed to plant matter comprising plant cells, including seed cells, rapeseed cells and tobacco cells, expressing a mammalian peptide, and dicotyledonous plants cells, including seed cells, rapeseed cells and tobacco cells, comprising a structural gene coding for a mammalian peptide, whereas claims 1-5 of U.S. Patent No. 5,550,038 are directed to methods utilizing dicotyledonous plant cells, including seed cells and rapeseed cells, comprising a structural gene coding for a mammalian peptide.

Claims 45-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 4,956,282. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 45-61 of the instant application are directed to plant matter comprising plant cells, including seed cells, rapeseed cells and tobacco cells, expressing a mammalian peptide, and dicotyledonous plants cells, including seed cells, rapeseed cells and tobacco cells, comprising a structural gene coding for a mammalian peptide, whereas claims 1-3 of U.S. Patent No. 4,956,282 are directed to methods utilizing dicotyledonous plant cells comprising a structural gene coding for a mammalian peptide.

Remarks

No claim is allowed.

Claims 45-61 are deemed free of the prior art, given the failure of the prior art to teach or suggest plant cells that express a mammalian peptide, as stated in the allowed parent applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 1, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638